Louisiana Medicaid
Roflumilast (Daliresp®)

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for roflumilast (Dalisresp®).

Additional Point-of-Sale edits may apply.

*This agent may have **Black Box Warnings** and/or may be subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety regulations. Please refer to individual prescribing information for details.*

Approval Criteria

- The recipient is 18 years of age or older on the date of the request; **AND**
- The recipient has a documented diagnosis of severe COPD associated with chronic bronchitis and a history of exacerbations. Documentation **stated on the request** must include, but is not limited to:
    - Date and results of the most recent FEV_1 (according to the Global Initiative for Chronic Obstructive Lung Disease™, an FEV_1 less than 50% predicted classifies COPD as severe to very severe); **AND**
    - A record of a history of COPD exacerbations, including dates of exacerbations; **AND**
    - Evidence that the recipient is receiving standard treatment for COPD (e.g., long-acting bronchodilator, beta agonist, and/or anticholinergic medications); **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient will not be concomitantly receiving a contraindicated or 'not recommended' medication while on roflumilast; **AND**
    - The recipient does not have a documented contraindication (such as moderate to severe liver impairment [Child-Pugh B or C]) to roflumilast.

Reauthorization Criteria

- The recipient continues to meet initial approval criteria; **AND**
- The prescriber **states on the request** that the recipient is established on the medication with evidence of a positive response to therapy.

Duration of initial and reauthorization approval: 12 months

References

Daliresp (roflumilast) [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; March 2020. https://den8dhaj6zs0e.cloudfront.net/50fd68b9-106b-4550-b5d0-12b045f8b184/704932ce-e104-4c6f-840a-575170971344/704932ce-e104-4c6f-840a-575170971344_viewable_rendition__v.pdf

Global Strategy for the Diagnosis, Management and Prevention of COPD, Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2017. https://goldcopd.org

Revision / Date	Implementation Date
Single PDL Implementation	May 2019
Formatting changes; updated reference / September 2021	January 2022